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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Barry Green

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EXAMINER

PAULS, JOHN A

ART UNIT

PAPER NUMBER

4114

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/758,856	<b>Applicant(s)</b> GREEN ET AL.	
	<b>Examiner</b> JOHN A. PAULS	<b>Art Unit</b> 4114	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9 December, 2005 and 2 October, 2006</u> .                    | 6) <input type="checkbox"/> Other: _____                          |



**DETAILED ACTION**

**Status of Claims**

1. This action is in reply to the application filed on 16 January, 2004
2. Claims 1 - 45 are currently pending and have been examined.

**Information Disclosure Statement**

3. The Information Disclosure Statements filed on 9 December, 2005 and 2 October, 2006 have been considered. Initialed copies of the Form 1449 are enclosed herewith.

***Drawings***

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include numerous reference character(s) not mentioned in the description. Numerous steps shown in the drawings are not described in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
5. Figure 6 requires correction in order to reflect the written description. See the 112 2<sup>nd</sup> rejection below.

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***Specification***

6. The disclosure is objected to because of the following informalities: use of acronyms without any definition including: SMS/text (Short Message Service); HIPAA (Health Insurance Portability and Accountability Act); PCI (Peripheral Component Interconnect); physician ME number (Medical Education); IVR (Interactive Voice Response); FTP (File Transfer Protocol); BBS (Bulletin Board Service). For purposes of this examination, Examiner assumes the definitions shown in parenthesis after each acronym.
7. Appropriate correction is required.

***Claim Objections***

8. Claims 4, 12, 26 and 34 are objected to because of the following informalities: use of acronyms. For purposes of this examination, Examiner assumes the definitions in parenthesis after each acronym as shown in the Specification Objection above. Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

9. 35 U.S.C. 101 reads as follows:  
  
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
10. Claims 1 - 45 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.
11. Claims 1 – 19 are directed to “readable media having instructions” The claims may constitute computer programs representing computer listings per se. Such descriptions or expressions of the programs are not physical “things”. They are neither computer components nor statutory processes, as they are not “acts” being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and other claimed elements of a computer, which permit the computer program’s functionality to be realized. See Lowry, 32 F.3d at 1583-84, 32 USPQ2d at 1035

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12. Claims 20 - 45 are directed to a method. However, the recited steps of the method are held to be non-statutory subject matter because the recited steps of the method are (1) not tied to another statutory class (such as a particular apparatus) or (2) not transforming the underlying subject matter (such as an article or materials ) to a different state or thing.

***Claim Rejections - 35 USC § 112***

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 2, 4, 5, 6, 24, 26, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “*production file*” is vague and indefinite. Examiner cannot determine the metes and bounds of the invention. The specification discloses that the production file is created unique for each contact channel as referenced in 6.06 and 6.07 (Figure 6). However, Figure 6 makes no reference to a “production file”. It is unclear what information is included in this file. For purposes of this examination, Examiner assumes that “*production file*” includes: “patient personal contact information” (Step 6.04) as well as “scripting, survey, text, code or recording” material (Step 6.07).

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**17. Examiner's Note:** The Examiner has pointed out particular references contained in the prior art of record within the body of this action for the convenience of the Applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply. Applicant, in preparing the response, should consider fully the entire reference as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

**18.** Claims 1, 2, 7 - 9, 13, 14, 19, 20 – 24, 29 – 31, 36 – 39, 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walden et al. (US PG PUB 2003/0036923 A1) and in further view of Richards et al. (US PG PUB 2003/0061006 A1).

#### **CLAIMS 1 and 20**

Walden as shown discloses a system and method for monitoring compliance with a pharmaceutical regimen. Walden discloses the following limitations:

- *identifying if an individual is eligible for a regimen contact based on an expressed contact management preference set forth in a database record associated with that individual; (see at least Walden paragraph 0020, 0068, 0069 and 0073);*
- *identifying a channel by which the individual is to be contacted; (see at least Walden paragraph 0073);*
- *selecting a contacting media to be used when contacting the individual considering the channel identified and a schedule of the regimen; (see at least Walden paragraph 0073, 0084 and 0085);*
- *attempting to contact the individual via the identified channel using the selected contacting media; (see at least Walden paragraph 0085);*

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- *providing informational materials concerning the regimen including information that specifies one or more means by which an individual registers with a regimen compliance network; (see at least Walden paragraph 0038 and 0075);*
- *accepting registration information from the individual by a means specified in the informational materials; (see at least Walden paragraph 0069);*
- *storing the registration information in a database associated with the regimen compliance network, the registration information including a contact management preference; when the stored registration information identifies the individual as being eligible for a regimen contact; (see at least Walden paragraph 0076 and 0073).*

Walden as shown discloses the limitations shown above. Walden does not specifically disclose the following limitation, however Richards does:

- *updating a touch history table within a database wherein the touch history table is utilized to track: which individuals are to be contacted, whether a contact procedure has been utilized in connection with that individual, and results of an attempted contact; (see at least Richards paragraph 0048 and 0050 - 0053);*

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the compliance system of Walden with the evaluation system of Richards to include a client data module because it would provide a positive mechanism for tracking contacted patients.

#### **CLAIMS 2 and 24**

The combination of Walden/Richards discloses the limitations shown above. Walden also discloses:

- *the contacting media comprises a production file; (see at least Walden paragraph 0085).*

Examiner notes that the production file contains queries unique to each contact channel. Walden discloses that the queries depend on the access method selected by the patient.

#### **CLAIMS 7 and 29**

The combination of Walden/Richards discloses the limitations shown above. Walden also discloses:

- *the instructions operate at predefined times to update compliance tracking data; (see at least Walden paragraph 0110 and 0116);*



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**CLAIMS 8 and 30**

The combination of Walden/Richards discloses the limitations shown above. Walden also discloses:

- *compliance tracking data is updated by*
  - *processing returned disposition files from a day's contact campaigns; (see at least Walden paragraph 0034 thru 0038);*
  - *posting dispositions to the touch history table; (see at least Walden paragraph 0034 thru 0038);*
  - *posting batch summary reports to provide a comprehensive reconciliation of contact dispositions by contact type and disposition code; (see at least Walden paragraph 0037 and 0038);*

**CLAIMS 9 and 31**

- *the instructions attempt a further contact with the individual, by a channel specified by the individual, in the event that the individual was unable to be reached by a first attempt; (see at least Walden paragraph 0116);*

**CLAIMS 13 and 36**

- *the instructions provide a graphical user interface accessible via a Web site by which the individual may supply contact preferences; (see at least Walden paragraph 0082 and 0119);*

**CLAIMS 14 and 39**

- *the instructions cause a pharmacy to be contacted to auto refill a prescription for a drug in response to the instructions identifying that an individual's record specifies an auto refill pharmacy and the individual is scheduled for a prescription refill based on a regimen dosage duration and a system calculated lag time; (see at least Walden paragraph 0111 thru 0115);*

**CLAIMS 19 and 44**

- *the instructions are adapted to capture retrieval confirmation information from the pharmacy; (see at least Walden paragraph 0078 and 0079);*

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**CLAIM 21**

- *the instructional materials include a process code which is indicative a physician; (see at least Walden paragraph 0068 and 0073).*

The combination of Walden/Richards does not specifically disclose a “*process code*”, but does disclose identification information for the physician. It would be obvious to one of ordinary skill in the art to modify Walden/Richards with a physician code or identifier (process code) so that the particular physician can be identified with a particular patient because knowing the patient-physician relationship is necessary in order to communicate relevant information to the physician about the patient.

**CLAIM 22**

The combination of Walden/Richards discloses the limitations shown above. Walden also discloses:

- *the process code is provided during individual registration and allows the regimen compliance network to establish physician normalization data; (see at least Walden paragraph 0068 and 0073).*

The combination of Walden/Richards does not specifically disclose a “*process code*” or “*normalization data*” per se, but does disclose identification information for the physician. It would be obvious to one of ordinary skill in the art to modify Walden/Richards with a physician code or identifier (process code) so that the particular physician can be identified with a particular patient or a particular type of patient and the type of information relevant to that type of patient because knowing the patient-physician relationship is necessary in order to communicate relevant information to the physician about the patient and to communicate relevant information to the patient about the particular disease or condition being treated..

**CLAIM 23**

The combination of Walden/Richards discloses the limitations shown above. Walden also discloses:

- *the regimen comprises a drug prescription; (see at least Walden paragraph 0031);*

**CLAIM 37**

The combination of Walden/Richards discloses the limitations shown above. Walden also discloses:

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- *a means by which an individual registers with the regimen compliance network comprises transmitting via mail information including contact preferences for entry into the regimen compliance network; (see at least Walden paragraph 0073 and 0079);*

**CLAIM 38**

The combination of Walden/Richards discloses the limitations shown above. Walden also discloses:

- *a means by which an individual registers with the regimen compliance network comprises phoning a representative of the regimen compliance network to supply information including contact preferences for entry into the regimen compliance network; (see at least Walden paragraph 0073 and 0083);*

**CLAIM 45**

The combination of Walden/Richards discloses the limitations shown above. Walden also discloses:

- *registering a physician with the regimen compliance network and indicating a correspondence between registered individuals and registered physicians; (see at least Walden paragraph 0073 and 0076).*

The combination of Walden/Richards does not specifically disclose registering a physician per se, but does disclose identification information for the physician. It would be obvious to one of ordinary skill in the art to modify Walden/Richards with a physician registration so that the particular physician can be identified with a particular patient because knowing the patient-physician relationship is necessary in order to communicate relevant information to the physician about the patient.

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19. Claims 3 - 6 and 25 - 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walden et al. (US PG PUB 2003/0036923 A1) and in further view of Richards et al. (US PG PUB 2003/0061006 A1) and in further view of **Official Notice**.

#### **CLAIMS 3 and 25**

The combination of Walden/Richards as shown discloses the limitations shown above. Walden/Richards does not disclose the following limitations:

- *a selected individual's record indicates that the individual has opted out of the process in a prior contact event.*

The combination of Walden/Richards does not disclose that the system indicates that the patient has opted out of the process per se, however, Walden/Richards does disclose that the system indicates that the patient has not filled the prescription and notifies the doctor (see at least Walden paragraph 0081). Examiner takes **Official Notice** that it is old and well known in the medical arts to track and take appropriate actions when participants in any survey opt out of the process. Therefore, it would have been obvious to one of ordinary skill in the arts at the time of the invention to modify the compliance and monitoring system of Walden/Richards with the opt out option of the **Official Notice** because tracking participants who have opted out of the process will make the compliance and monitoring system more accurate.

#### **CLAIMS 4 and 26**

The combination of Walden/Richards as shown discloses the limitations shown above. Walden/Richards does not disclose the following limitations:

- *the instructions post the production file via a virtual private network to either a secured FTP or secured BBS folder.*

The combination of Walden/Richards does not disclose that the production file (queries relevant to each contact channel) are posted to either a file transfer protocol or a bulletin board system folder per se. However, Walden/Richards does disclose that the queries can be delivered via the Internet or email (see at least Walden paragraph 0082). Examiner takes **Official Notice** that it is well known in the arts to use file transfer protocols and bulletin board systems to electronically deliver information to a recipient.

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Therefore, it would have been obvious to one of ordinary skill in the arts at the time of the invention to modify the compliance and monitoring system of Walden/Richards with the electronic delivery of the **Official Notice** because file transfer protocols and bulletin board systems are known methods for solving the problem of delivering information electronically.

#### **CLAIMS 5 and 27**

The combination of Walden/Richards/Official Notice discloses the limitations shown above. Additionally, Walden discloses the following limitation:

- *the production file is imported to a predictive dialer application that works in connection with a telephone network interface whereby the contact may be administered in the manner that has been defined by the individual; (see at least Walden paragraph 0085).*

Examiner notes that the predictive dialer application in the present application is the same as the automated telephone interface of Walden.

#### **CLAIMS 6 and 28**

The combination of Walden/Richards/Official Notice discloses the limitations shown above. Additionally, Walden discloses the following limitation:

- *the production file is imported to a distribution application that works in connection with a computer network interface whereby the contact may be administered in the manner that has been defined by the individual; (see at least Walden paragraph 0085).*

- 20.** Claims 10 – 12 and 32 - 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walden et al. (US PG PUB 2003/0036923 A1) and in further view of Richards et al. (US PG PUB 2003/0061006 A1) and in further view of Teagarden (US 6014631 A).

#### **CLAIMS 10 - 12 and 32 - 35**

The combination of Walden/Richards as shown discloses the limitations shown above. Walden/Richards does not disclose the following limitations, however Teagarden does:

- *the instructions cause a physician of the individual to be notified that a scheduled, compliance checking contact went unanswered; (see at least Teagarden column 11 line 36 - 41);*

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- *the physician notification is transmitted by electronic mail; (see at least Teagarden column 11 line 11 - 16);*
- *the physician notification is performed using an IVR phone call; (see at least Teagarden column 11 line 11 - 16);*
- *using a facsimile transmission to provide the physician notification. (see at least Teagarden column 11 line 36 - 41).*

It would be obvious to one of ordinary skill in the art at the time of the invention to combine the compliance and monitoring system of Walden/Richards with the physician notification system of Teagarden because notifying the physician of an adverse action by any of the normal means available would allow the physician to intercede in the patients care in a timely manner.

**21.** Claims 15 – 18 and 40 - 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walden et al. (US PG PUB 2003/0036923 A1) and in further view of Richards et al. (US PG PUB 2003/0061006 A1) and in further view of Sussman (US PG PUB 2003/0018495 A1).

**CLAIMS 15 - 18 and 40 - 43**

The combination of Walden/Richards as shown discloses the limitations shown above. Walden/Richards does not disclose the following limitations, however Sussman does:

- *the calculated lag time is defined at a brand-level for the prescribed drug; (see at least Sussman paragraph 0112);*
- *the pharmacy is contacted via an email; (see at least Sussman paragraph 0040);*
- *the pharmacy is contacted via a facsimile transmission; (see at least Sussman paragraph 0005).*

It would be obvious to one of ordinary skill in the art at the time of the invention to combine the compliance and monitoring system of Walden/Richards with the pharmacy communication system of Sussman because notifying the pharmacy that a refill is required by any of the normal means available would allow the prescription to be filled in a timely manner.

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The combination of Walden/Richards/Sussman discloses the limitations shown above. The combination of Walden/Richards/Sussman does not disclose:

- *the calculated lag time is defined by a physician for the individual.*

However, it would be obvious to one of ordinary skill in the arts at the time of the invention that a physician ordering a prescription could order any number of refills or that refills should be filled on a prescribed time table. Therefore it would be obvious to one of ordinary skill in the arts at the time of the invention to modify Walden/Richards/Sussman so that a physician may order prescription refills on a prescribed time table because it would allow the physician to do follow-up before continuing any particular regimen.

### CONCLUSION

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **John A. Pauls** whose telephone number is **571-270-5557**. The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JAMES A. REAGAN** can be reached at **571.272.6710**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair> . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

Any response to this action should be mailed to:

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**Washington, D.C. 20231**

or faxed to **571-273-8300**.

Hand delivered responses should be brought to the **United States Patent and Trademark Office Customer Service Window**:

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Date: 12 January, 2009

/JOHN A. PAULS/

Examiner, Art Unit 4114

/James A. Reagan/

Supervisory Patent Examiner, Art Unit 4114